# Mouth Guard Tied to Shorter Second Stage

BY HEIDI SPLETE

WASHINGTON — Women who were able to bite down on a mouth guard had a significantly shorter second stage of labor, compared with women who didn't use a mouth guard, based on the results of a randomized trial of 64 women with uncomplicated singleton pregnancies.

Developing a way to help women push harder may shorten the second stage of labor and reduce the number of cesarean or instrumental deliveries that are associated with a longer second stage, Dr. Janna Mudd said at the annual meeting of the Society of Obstetric Anesthesia and Perinatology.

**'I was surprised how many people seemed very enthusiastic and willing to try anything to avoid an operative delivery.'**

"We wanted to come up with a method that would maximize maternal expulsive effort," she explained.

Previous studies have shown that wearing a mouth guard increases the isometric strength of different muscle groups, and the researchers hypothesized that the device (a plastic mouth guard similar to those used in sports) would encourage women to push harder during the second stage of labor.

To test this theory, Dr. Mudd and her colleagues at the University of Maryland in Baltimore randomized women at a single hospital in Baltimore to wear or not wear a mouth guard during the second stage of labor. The women were nulliparous with uncomplicated singleton term pregnancies, and an average gestational age of 39 weeks. There were no significant obstetrical demographic differences between the two groups, Dr. Mudd commented.

The researchers excluded women with diabetes, preeclampsia, or other comorbidities; those whose babies were large for gestational age; or those who had shoulder dystocia or other potential complications. A total of 38 women (19 in each group) were evaluated during the second stage of labor. Overall, the average duration of the second stage was 19 minutes in the mouth guard group vs. 31 minutes in the control group.

Each of the women in the study had received an epidural, and their pushing was directed by a doctor or midwife. The women were instructed to start pushing when they were deemed fully dilated based on a digital exam.

There were no significant differences in birth weight, head circumference, Apgar scores, umbilical arterial and venous pH, and rate of NICU admission among infants of women who used the mouth guards, compared with those women who did not wear a mouth guard.

"We also were very interested in patient satisfaction," Dr. Mudd said. "I was surprised how many people seemed very enthusiastic and willing to try anything to avoid an operative deliver,"

Overall, the patients were very satisfied with the device and said they thought that wearing it helped them to focus while pushing, although some women reported discomfort and nausea while using the mouth guard. On average, the women who used the mouth guards rated their satisfaction as 4 on a scale of 1-5.

The researchers considered three possible mechanisms of action for the impact of a mouth guard on the second stage of labor: a direct effect on the muscles, a secondary effect on posture, and increased endurance during isometric muscle activity.

In response to a question from the audience, Dr. Mudd noted that she had no explanation for why the second stage of labor in the study population as a whole was shorter than average for nulliparous women. (The American Pregnancy Association says the second stage lasts anywhere from approximately 20 minutes to 2 hours.)

The study was limited by its small size, and more research is needed to confirm the results, Dr. Mudd said.Factors to consider in future studies include measuring the uterine pressure to identify whether the expulsive effort is greater in women who wear mouth guards during the second stage of labor, she commented.

The researchers had no financial conflicts to disclose related to the study. ■

## DRUGS, PREGNANCY, AND LACTATION

# Treating Morning Sickness

Currently, no drug approved by the Food and Drug Administration is available for treating morning sickness.

Bendectin, the combination of the antihistamine doxylamine with pyridoxine (vitamin $B_6$)—used in the United States and Canada in the 1960s and 1970s for treating nausea and vomiting of pregnancy—was pulled from the market because of litigious claims. But this combination has been shown to be safe in large studies conducted since that time, and has been approved and available continuously as Diclectin in Canada.

BY GIDEON KOREN, M.D.

Doxylamine is an older antihistamine and has central nervous system effects, including sedation, and Diclectin is not yet approved in the United States. Therefore, there is room for alternatives for treating nausea and vomiting in pregnancy (NVP). Currently, trials are being conducted in the United States in a process aimed at reintroducing the combination of doxylamine and pyridoxine to the U.S. market, in view of its impressive safety record.

Metoclopramide, a prokinetic drug used for more than 40 years to treat nausea and vomiting due to various causes, is one alternative to the doxylamine-pyridoxine combination. Because metoclopramide acts mostly through the gut, not the CNS, it has a physiologic advantage in terms of potential side effects and is the drug of choice for NVP in some countries, but not in North America, where it is usually used only for severe cases. It can be associated with extrapyramidal symptoms, which tend to be self-limited and have rarely been reported in the context of morning sickness.

To date, the safety data on the use of metoclopramide during pregnancy have been limited, based on studies involving about 800 pregnancies in the literature. But a large, retrospective cohort study published in June, conducted by investigators at Ben-Gurion University of the Negev, Beer-Sheva, Israel, in collaboration with the Motherisk program in Toronto, provided reassuring data regarding its safety during the first trimester of pregnancy.

The study linked medication database records for females aged 15-49 years who were members of a health maintenance organization in Southern Israel, with databases containing maternal and infant records for the medical center that serves the area.

Of the 81,703 infants born to these women between Jan. 1, 1998, and March 31, 2007, a remarkable 3,458 (4.2%) had been exposed to metoclopramide during the first trimester.

This number exceeded what we expected and created a rare opportunity to analyze the reproductive safety of this drug in a large study with good quality data and the ability to adjust for confounding factors, including parity, maternal age, and smoking status. The mean number of daily doses was about seven, and the mean age of the women was almost 28 years.

When compared with the infants of the 78,245 women in the HMO who had not taken metoclopramide during the first trimester, there was no increased risk of major or minor congenital malformations, low birth weight, preterm delivery, or perinatal death among the infants whose mothers had taken metoclopramide during the first trimester, after adjustment for confounding factors (N. Engl. J. Med. 2009;360:2528-35). The results did not change when pregnancy terminations were included.

Metoclopramide is another option for treating nausea and vomiting, the most common condition in pregnancy, which often receives inadequate attention from clinicians, despite studies showing NVP causes significant social and psychological morbidity. Clinicians who may be hesitant to prescribe an antiemetic for patients who are suffering from NVP should be able to prescribe with confidence a treatment for which more data are now available to support its safety.

An important consideration when treating women who have NVP is the impact that heartburn and reflux can have on the severity of these symptoms. Quite a few women who call the dedicated NVP line at Motherisk (800-436-8477) reported also having acid reflux symptoms, along with nausea and vomiting, which led to a study that demonstrated for the first time that heartburn and acid reflux can exacerbate the severity of nausea and vomiting.

The prospective study, published in the Canadian Journal of Gastroenterology in April, compared 194 women with NVP and heartburn, reflux, or both, with 188 women with NVP without heartburn or reflux. We found that the women with heartburn and reflux had significantly higher scores on scales that measured the degree of emesis and nausea, and significantly lower well-being scores, which our analysis determined was related to heartburn and reflux, not to preexisting GI conditions or symptoms, hyperemesis gravidarum in previous pregnancies, or other confounding factors (Can. J. Gastroenterol. 2009; 23:270-2) .

In another study that is in press, we also found that treating women who have reflux and heartburn associated with NVP with an $H_2$ receptor blocker or a proton pump inhibitor decreased nausea and vomiting dramatically, without the need for increasing the dose of the antiemetic.

The results of this study support managing acid reflux in women with these symptoms to help control nausea and vomiting—a strategy that has not received much consideration previously. Recent meta-analyses by Motherisk have shown that both $H_2$ blockers and proton pump inhibitors are safe during pregnancy, further supporting the management of reflux. ■

*DR. KOREN is a professor of pediatrics, pharmacy, pharmacology, medicine, and medical genetics at the University of Toronto. He heads the Research Leadership in Better Pharmacotherapy During Pregnancy and Lactation at the Hospital for Sick Children, Toronto, where he is director of the Motherisk program. He has received consulting and lecture fees, as well as grant support, from Duchesnay Inc., manufacturer of Diclectin.*